# Development of a Tailored HIV Prevention Intervention for Young Men NCT02842060

DATE: October 11, 2016

## **Consent to Participate in a Research Study**

## What is this study about?

You are invited to be a part of a research study that focuses on delivering tailored HIV/STI prevention messages for young men who meet male partners online. The purpose of the study is to develop and pilot test a culturally acceptable online resources that helps participants to (1) learn about comprehensive sex education, (2) reflect on their partner-seeking behaviors, and 3) develop behavioral skills to practice safer-sex decision making. We are asking you to participate because you currently are a young male between the ages of 18 and 24 who is single, and has had at least one same-sex partner in the past 6 months.

## What does my participation in this study involve?

If you agree to be part of the study, you will receive access to a sexual health education website, which will discuss basic information on safer sex and HIV prevention strategies. The website also will discuss dating strategies and opportunities to improve your overall well-being. The content of this sexual health education website will be delivered over 6 sessions.

You will be asked to complete 3 follow-up surveys at 30, 60 and 90 days after completing the program. Each survey should take between 15-20 minutes to complete. The survey topics will include your demographics (such as race/ethnicity, income, and education level), general mood, and online behaviors. We will also be asking questions about sensitive and explicit information regarding your HIV status, sexual and substance use behaviors, and your sexual partner history.

#### What is the potential risk of participating in this study?

Sometimes answering questions about sexual and substance use behaviors can cause distress or raise concerns about confidentiality. At any point during the web surveys, you may skip any question you do not want to answer, and you are free to stop your participation in the research at any time. No identifying information about you will appear in the working data files used in the study. To offset the risk of distress, you will be provided on the website with a link to the Center for Sexuality and Health Disparities, which has a special page listing referral agencies, such as mental health centers, substance use facilities and support groups, and HIV/STI testing and counseling facilities.

## How will you protect my privacy?

Answering questions about these topics can be difficult. To protect your privacy, the information we collect in this study will be considered confidential and will initially only be shared by the research team, which includes the Principal Investigator, research staff, and graduate students at the Center for Sexuality and Health Disparities (SexLab). We may also store and use your information for future research at the University of Michigan. We might also share it with other researchers outside the University of Michigan, but we will not share any information that could identify you. We will ask for your home and email address for administrative purposes (e.g., to send your compensation, ensure you only fill out the survey once, linking Census data). Additionally, home addresses will only be used to link Census information to our data in order to understand neighborhood differences. Your home address will not be attached to any of your responses, meaning that we will delink address information from other data you provide us and store it in a separate file. Email addresses are necessary for sending you an electronic gift card upon completion of the questionnaire, and will be kept for five years, given your consent. Personal information will not be linked to any of your answers or used for additional correspondence after the completion of the study unless you give us permission below. We will not ask for your name.

There are some reasons why people other than the researchers may need to see information you provided as part of the study. This includes organizations responsible for making sure the research is done safely and properly, including the University of Michigan. However, to help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, we cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we may not use the Certificate to withhold that information. The Certificate of Confidentiality does not govern the voluntary disclosure of information by you that is not included in the survey, nor does it represent an endorsement of the research by the Secretary of Health and Human Services.

#### Will I directly benefit from participating in this study?

While you may not receive a direct benefit from participating in this research, some people find answering these questions to be a valuable experience. We hope that this study will help us understand partner-seeking and safer sex behaviors among young men, and develop culturally competent information.

#### Will I be compensated for my time?

You have the potential to be paid \$90 total. You will be paid \$30 for completing the initial evaluation, \$15 for the 30-day, \$20 for the 60-day, and \$25 for the 90-day evaluations. Payment will be given in the form of a MasterCard e-gift card upon completion of each assessment. This e-gift card may be used directly for online purchases or may be mailed to you as a prepaid card. You must finish each assessment to receive your compensation, but you can still skip any question you do not want to answer. If at any time you choose not to finish the assessment, you will not receive this compensation. We will send the gifts cards electronically to the email address you provide when creating your survey account. We will not disclose or sell your e-mail or home address to any third parties.

#### What will the researchers do with the data?

We plan to publish the results of this study, but will not include any information that could identify you or any individual in these publications. Your e-mail address, web-survey account, and any other personal identifiers will be stored in a password-protected University of Michigan server. This information will be destroyed after five years. Your survey answers will not be tied to this personal information. All your answers will be kept on a computer that is password-protected. By consenting to this research, you allow the researchers to keep and analyze de-identified study data indefinitely.

#### What if I change my mind regarding my participation in this study?

Participating in this research is completely voluntary. Even if you decide to participate now, you may change your mind and stop at any time. If you do choose to stop participating in this study, data collected from the study will be retained and used for analyses. However, if you prefer that your data be destroyed and not used, we will honor your request.

### Who can I contact if I have questions about the study?

You will be e-mailed a link with a copy of this consent document for your records and one copy will be kept with the study records. If you have questions about this research, you can contact the Principal Investigator:

Jose Bauermeister, M.P.H., Ph.D.
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The project website also provides links to various community resources that you might find helpful for yourself or for your friends. Simply go to the website and click on the "Resources" link.

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board by phone: (866) 936-0933, e-mail: <a href="mailto:irbhsbs@umich.edu">irbhsbs@umich.edu</a>, or post at:

University of Michigan Institutional Review Board NCRC 2800 Plymouth Road, Suite 1169 Ann Arbor, MI 48109-2800

Do you agree to participate in the study?
Yes, I agree to participate in the study.  No, I do not agree to participate in the study.
Do you agree to allow us to keep your email address and contact you about future research opportunities
in the next five years?
Yes, you may keep my email address.
No, you may not keep my email address.